



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 12 1999

1264 '99 MAR 23 P2:13

Ms. Anna M. Micciulla
Quality and Regulatory Affairs Manager
Selfcare, Inc.
200 Prospect Street
Waltham, Massachusetts 02453

Dear Ms. Micciulla:

This is in response to your letter of February 16, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Selfcare, Inc. is making the following claims, among others, for the products:

Protegra® Cardio

"Fights LDL cholesterol build-up"
"...help protect against LDL cholesterol build-up"

SoyCare™ Prostate

"Reduces frequency of urination"
"Minimizes discomfort"

Stresstabs® Menopause

"...alleviate menopausal discomforts"
"...reduces cramping"

Stresstabs® PMS

"...lessens cramping, reduces breast tenderness, and swelling & water retention"
"Helps reduce swelling, breast tenderness and water retention"
"...lessen cramping and irritability"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that these products are intended to treat, prevent, cure, or mitigate disease, namely atherosclerosis and arterial plaque formation, symptomatic disorders of

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menopause, symptomatic disorders of the prostate (i.e., benign prostatic hypertrophy), and premenstrual syndrome (i.e., PMS). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Dorsey)

HFV-228 (SBenz)

HFV-232 (ABrown)

f/t:HFS-456:rjm:3/12/99:docname:64102.adv:disc36

Selfcare, Inc.

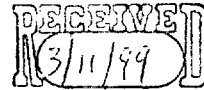
100 West Street
Boston, Massachusetts 02453

Telephone 781-647-3900
Facsimile 781-647-3939

64/02



February 16, 1999



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Sir or Madam:

This notification is being made, as required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, that Selfcare, Inc. intends to market dietary supplement products with the following labeling statements of nutritional support:

Protegra® Cardio

High Potency Heart Support Vitamin & Mineral Supplement

- Supports healthy arteries.
- Fights LDL cholesterol build-up.
- Helps maintain low homocysteine levels.
- Vitamins B6, B12 and Folic Acid break down homocysteine daily to support healthy arteries.
- Vitamins E, C and Beta Carotene are recognized as the most powerful antioxidant vitamins to help protect against cell damage.
- Vitamins E, C, & Beta Carotene plus Selenium, Zinc, Copper & Magnesium help protect against LDL cholesterol build-up.

SoyCare™ Prostate

Herb and Nutritional Supplement

- Reduces frequency of urination.
- Minimizes discomfort.
- Helps maintain healthy prostate cells & tissues.
- SoyCare™ Prostate is formulated to promote normal, healthy prostate function and comfort.
- Saw Palmetto helps maintain normal urinary flow.

- Saw Palmetto supports healthy prostate function.
- Soy-Isoflavones helps maintain healthy prostate tissues and cells.
- Vitamin E and Selenium help protect prostate cells.
- Vitamin E and Selenium work together as antioxidants to help protect your entire body against free-radical build-up.

Stresstabs® Menopause

Herbal and Mineral Supplement

- Promotes a stress-free transition
- Supports restful sleep, ongoing positive outlook, and healthy bones
- Ease the transition through menopause
- Black Cohosh helps alleviate menopausal discomforts
- Black Cohosh contributes to a more normal body temperature and sleeping pattern
- St. John's Wort helps maintain a balanced emotional state
- St. John's Wort promotes a more positive outlook
- Magnesium reduces cramping
- Magnesium helps promote healthy bone structure

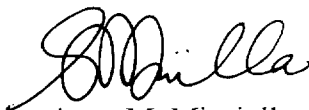
Stresstabs® PMS

Herbal and Mineral Supplement

- Promotes stress-free cycles
- Supports a positive mood, lessens cramping, reduces breast tenderness, and swelling & water retention
- Helps reduce swelling, breast tenderness and water retention.
- Encourages normal menstrual discharge
- Helps achieve more balanced cycles
- This herb and mineral supplement will help you achieve a more balanced cycle. Its Chaste Tree Berry extract reduces swelling and contributes to a positive mood. Calcium and magnesium in the formula lessen cramping and irritability by replenishing the supplies of these important minerals.

If you have any questions regarding this information please do not hesitate to contact me.

Best regards,



Anna M. Micciulla
Quality and Regulatory Affairs Manager
Selfcare, Inc.